Liza M. Walsh
Christine I. Gannon
Jessica K. Formichella
Lauren R. Malakoff
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, New Jersey 07102
(973) 757-1100
(973) 757-1090

Attorneys for Defendant
Teva Pharmaceuticals USA, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CORCEPT THERAPEUTICS, INC., ***Plaintiff,*** **v.** **TEVA PHARMACEUTICALS USA, INC.,** ***Defendant.***	**Civil Action No. 23-1505 (RMB) (LDW)** *Filed Electronically*

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT AND COUNTERCLAIMS

Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), answers the Complaint in Civil Action No. 23-1505 (Dkt. No. 1) brought by Plaintiff Corcept Therapeutics, Inc. ("Corcept"). Additionally, Teva asserts counterclaims for declaratory judgment of invalidity and non-infringement of U.S. Patent Nos. 10,842,800 ("the '800 patent") and 10,842,801 ("the '801 patent").

With respect to the allegations made in the Complaint, Teva states as follows:

Nature of the Action[1]

1. Teva admits that this purports to be an action for patent infringement under the patent laws of the United States, Title 35, United States Code. Teva admits that this action purports to relate to Abbreviated New Drug Application ("ANDA") No. 211436 filed by Teva with the FDA seeking approval to sell a generic version of Corcept's 300 mg mifepristone drug product. Teva denies any remaining allegations in paragraph 1 of the Complaint.

The Parties

2. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiff's allegations and therefore denies them.

3. Admitted.

4. The allegations in paragraph 4 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 21). Accordingly, no response to the allegations of this paragraph is required.

5. Admitted.

[1] This Answer reproduces the headings of the Complaint for convenience only. This reproduction of the headings should not be construed as an admission of any of the allegations in the Complaint.

6. Admitted as to Teva Pharmaceuticals USA, Inc. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 21). Thus, to the extent the allegations of this paragraph are directed to Teva Pharmaceutical Industries Ltd., no response to those allegations is required.

7. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiff's allegations about unidentified "other Teva entities" and therefore denies them.

8. Denied.

The Patents-in-Suit

9. Teva admits that the face of the '800 patent bears the title "Concomitant administration of glucocorticoid receptor modulators and CYP3A inhibitors" and states that the patent was issued to Corcept as assignee of the inventor Joseph K. Belanoff on November 24, 2020. Teva denies that the '800 patent was duly and legally issued. Teva admits that what appears to be a copy of the '800 patent is attached as Exhibit A to the Complaint.

10. Teva admits that the face of the '801 patent bears the title "Optimizing Mifepristone Absorption" and states that the patent was issued to Corcept as assignee of the inventors Joseph K. Belanoff, Robert Roe, and Caroline Loewy on November 24, 2020. Teva denies that the '801 patent was duly and legally issued. Teva admits that what appears to be a copy of the '801 patent is attached as Exhibit B to the Complaint.

The KORLYM® Drug Product

11. Teva admits that Corcept is identified by the FDA as the holder of approved New Drug Application ("NDA") No. 202107 for use of mifepristone tablets, which are sold under the trade name Korlym. Teva admits that Korlym is indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Teva

denies any remaining allegations in paragraph 11 of the Complaint. Teva further states that the claims of the patents in suit speak for themselves and denies the allegations of this paragraph to the extent they are inconsistent with the language of those claims.

12. Teva admits that the '800 and '801 patents are listed in the Orange Book entry for Korlym. Teva denies that the '800 and '801 patents are properly listed in the Orange Book entry for Korlym. Teva denies any remaining allegations of this paragraph.

Jurisdiction and Venue

13. The allegations in paragraph 13 of the Complaint constitute conclusions of law to which no answer is required. To the extent an answer is required, Teva admits that this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

14. The allegation in paragraph 14 of the Complaint that this Court has personal jurisdiction over Teva constitutes a conclusion of law to which no answer is required. To the extent an answer is required, Teva does not contest, for purposes of this action only, that the Court has personal jurisdiction over it. Teva admits that it is headquartered in New Jersey; that it is registered to do business in New Jersey; that its New Jersey Entity ID No. is 0100250184; that it has appointed a registered agent in New Jersey for receipt of service of process; and that it holds licenses in the State of New Jersey as a "manufacturer and wholesaler" and "wholesaler" of drugs, with License Nos. 5000583 and 5003436, respectively. Teva denies any remaining allegations of this paragraph.

15. The allegations in paragraph 15 of the Complaint constitute conclusions of law to which no answer is required. To the extent an answer is required, Teva does not contest, for purposes of this action only, that the Court has personal jurisdiction over it. Teva denies any remaining allegations of this paragraph.

16. Admitted.

17. Teva lacks knowledge or information sufficient to form a belief as to the truth of Plaintiff's speculative allegations and therefore denies them.

18. Teva admits that it has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction. Teva denies that it has availed itself of the benefits of this judicial district through the assertion of counterclaims.

19. Teva admits that it has previously brought actions for patent infringement in this district. Teva denies that it has availed itself of the benefits of this judicial district through its assertion of infringement claims.

20. The allegations in paragraph 20 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 21). Accordingly, no response to the allegations of this paragraph is required.

21. The allegations in paragraph 21 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 21). Accordingly, no response to the allegations of this paragraph is required.

22. The allegations in paragraph 22 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 21). Accordingly, no response to the allegations of this paragraph is required.

23. Denied.

24. Denied as to Teva Pharmaceuticals USA, Inc. Certain allegations in paragraph 24 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 21). Accordingly, no response to those allegations is required.

25. The allegations in paragraph 25 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 21). Accordingly, no response to the allegations of this paragraph is required.

26. Denied.

27. The allegations in paragraph 27 of the Complaint constitute conclusions of law to which no answer is required. To the extent an answer is required, Teva does not contest, for purposes of this action only, that venue is proper in this judicial district.

Acts Giving Rise To This Suit

28. Teva admits that it filed with the FDA Abbreviated New Drug Application ("ANDA") No. 211436 seeking approval to sell a generic version of Corcept's 300 mg mifepristone drug product. Teva states that ANDA No. 211436 speaks for itself and denies the allegations of this paragraph to the extent they are inconsistent with that ANDA. Teva denies the remaining allegations in paragraph 28 of the Complaint.

29. Teva admits that it first sent written notice of its ANDA and its paragraph IV certifications to Plaintiff on or about January 31, 2018. Teva states that the notice letter speaks for itself and denies the allegations of this paragraph to the extent they are inconsistent with the letter. Teva denies the remaining allegations in paragraph 29 of the Complaint.

30. Teva admits that it sent what Corcept describes as a second written notice of its ANDA and a paragraph IV certification to Plaintiff on or about May 14, 2018. Teva states that the

notice letter speaks for itself and denies the allegations of this paragraph to the extent they are inconsistent with the letter. Teva denies the remaining allegations in paragraph 30 of the Complaint.

31. Teva admits that it sent what Corcept describes as a third written notice of its ANDA and a paragraph IV certification to Plaintiff on or about January 14, 2019. Teva states that the notice letter speaks for itself and denies the allegations of this paragraph to the extent they are inconsistent with the letter. Teva denies the remaining allegations in paragraph 31 of the Complaint.

32. Teva admits that it sent what Corcept describes as a fourth written notice of its ANDA and a paragraph IV certification to Plaintiff on or about May 8, 2019. Teva states that the notice letter speaks for itself and denies the allegations of this paragraph to the extent they are inconsistent with the letter. Teva denies the remaining allegations in paragraph 32 of the Complaint.

33. Teva admits that it sent what Corcept describes as a fifth written notice of its ANDA and a paragraph IV certification to Plaintiff on or about June 20, 2019. Teva states that the notice letter speaks for itself and denies the allegations of this paragraph to the extent they are inconsistent with the letter. Teva denies the remaining allegations in paragraph 33 of the Complaint.

34. Teva admits that it sent what Corcept describes as a sixth written notice of its ANDA and a paragraph IV certification to Plaintiff no earlier than December 19, 2019. Teva states that the notice letter speaks for itself and denies the allegations of this paragraph to the extent they are inconsistent with the letter. Teva denies the remaining allegations in paragraph 34 of the Complaint.

35. Teva admits that it sent what Corcept describes as a seventh written notice of its ANDA and a paragraph IV certification to Plaintiff on or about June 12, 2020. Teva states that the notice letter speaks for itself and denies the allegations of this paragraph to the extent they are inconsistent with the letter. Teva denies the remaining allegations in paragraph 35 of the Complaint.

36. Teva admits that it filed with the FDA ANDA No. 211436 seeking approval to sell Korlym before the expiration of the patents that were listed in the Orange Book entry for Korlym at that time. Teva states that the notice letters speak for themselves and denies the allegations of this paragraph to the extent they are inconsistent with ANDA No. 211436. Teva denies the remaining allegations in paragraph 36 of the Complaint.

37. Denied as to Teva Pharmaceuticals USA, Inc. Certain allegations in paragraph 37 of the Complaint are directed to Teva Pharmaceutical Industries Ltd. By stipulation of the parties, the Court has dismissed Teva Pharmaceutical Industries Ltd. from this action without prejudice (Dkt. No. 21). Accordingly, no response to those allegations is required.

Count I: Infringement of the '800 Patent

38. In response to paragraph 38 of the Complaint, Teva incorporates by reference paragraphs 1 through 37 of this Answer as if fully set forth herein

39. Denied.

40. Teva admits that there is an actual case or controversy between the parties, but denies the remaining allegations in paragraph 40 of the Complaint.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

Count II: Infringement of the '801 Patent

46. In response to paragraph 46 of the Complaint, Teva incorporates by reference paragraphs 1 through 45 of this Answer as if fully set forth herein

47. Denied.

48. Teva admits that there is an actual case or controversy between the parties, but denies the remaining allegations in paragraph 48 of the Complaint.

49. Denied.

50. Denied.

51. Denied.

52. Denied.

53. Denied.

PRAYER FOR RELIEF

This section of Plaintiff's Complaint constitutes Prayers for Relief that do not require a response. Teva denies that Plaintiff is entitled to any of the requested relief or any other relief.

GENERAL DENIAL

Each averment or allegation contained in Plaintiff's Complaint that is not specifically admitted in this Answer is denied.

AFFIRMATIVE AND OTHER DEFENSES

FIRST DEFENSE

(Failure to State a Claim)

Plaintiff fails to state a claim upon which relief can be granted.

SECOND DEFENSE

(Noninfringement of the '800 patent)

Teva has not infringed, directly or indirectly, any valid claim of the '800 patent, and is not liable for any infringement thereof.

THIRD DEFENSE

(Noninfringement of the '801 patent)

Teva has not infringed, directly or indirectly, any valid claim of the '801 patent, and is not liable for any infringement thereof.

FOURTH DEFENSE

(Invalidity of the '800 patent)

Each claim of the '800 patent is invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

FIFTH DEFENSE

(Invalidity of the '801 patent)

Each claim of the '801 patent is invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112.

RESERVATION OF RIGHTS

Teva reserves the right to assert additional defenses as may be warranted by discovery or other further factual investigation in this action.

COUNTERCLAIMS

Defendant and Counterclaim Plaintiff Teva Pharmaceuticals USA, Inc. ("Teva") asserts the following counterclaims against Plaintiff and Counterclaim-Defendant Corcept Therapeutics, Inc. ("Corcept").

NATURE OF THE COUNTERCLAIMS

1. These counterclaims include claims for declaratory judgment that Teva has not infringed U.S. Patent Nos. 10,842,800 ("the '800 patent") and 10,842,801 ("the '801 patent") (collectively, the "Asserted Patents") and that the Asserted Patents are invalid.

THE PARTIES

2. Teva is a corporation organized and existing under the laws of Delaware, with its principal place of business at 400 Interpace Parkway, #3, Parsippany, NJ 07054.

3. On information and belief, and as alleged by Counterclaim-Defendant, Corcept is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 149 Commonwealth Dr., Menlo Park, CA 94025.

4. Counterclaim-Defendant is the entity that filed the Complaint in this action on or about March 17, 2023.

JURISDICTION AND VENUE

5. These counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202.

6. This Court has subject-matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

7. Corcept has availed itself of this forum in this action and is therefore subject to personal jurisdiction in this District for purposes of these counterclaims.

8. To the extent that venue is proper in connection with Corcept's Complaint, it is equally proper for these counterclaims under 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

A. The Hatch-Waxman Framework, Corcept's NDA, and Teva's ANDA

9. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301, *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 335(b)(2) and 355(j), and 35 U.S.C. § 271(e), establish procedures designed to facilitate competition in prescription-drug markets from lower-priced generic drugs.

10. The Hatch-Waxman Act also provides a framework for the holders of pharmaceutical patents to enforce their patents against generic competitors. As part of this framework, an NDA applicant is permitted to list in the Orange Book "any patent which claims the drug for which the applicant submitted the [NDA] or which claims a method of using such drug." *Id.* § 355(b)(1). The FDA does not examine the validity or propriety of Orange Book patent submissions. It performs only the ministerial role of listing in the Orange Book any patents that the NDA holder claims cover its approved drug.

11. The Orange Book states that the NDA holder of NDA No. 202107 is Corcept. The proprietary name listed for NDA No. 202107 is "Korlym." The Orange Book listing for NDA No. 202107 states that the active ingredient is "mifepristone" and that the dosage is 300 mg in the form of "tablets."

12. On or about February 17, 2012, the FDA approved the NDA No. 202107 filed for Corcept's mifepristone drug, sold under the name brand Korlym, for a single indication: to treat

hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.

13. Under the Hatch-Waxman Act, when filing an ANDA, a generic manufacturer seeking to enter the market must demonstrate that its proposed generic is bioequivalent to the approved drug, and must certify whether its generic drug would infringe any patents then listed in the Orange Book associated with the approved drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii).

14. The Hatch-Waxman Act also requires each ANDA applicant to certify that: (1) the relevant Orange Book entry at the time of application contains no patent information ("Paragraph I certification"); (2) the patents then listed have expired ("Paragraph II certification"); (3) the applicant will not enter the market until the patents then listed expire ("Paragraph III certification"); or (4) the applicant believes that the patents then listed are invalid or will not be infringed by the proposed generic ("Paragraph IV certification"). *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV).

15. On or about December 15, 2017, Teva filed ANDA No. 211436 seeking FDA approval to market generic mifepristone tablets, 300 mg, prior to the expiration of the patents then listed in the Orange Book entry for Korlym.

16. Teva's ANDA included a Paragraph IV certification.

B. Corcept Files First Complaint Against Teva

17. In response to Teva's ANDA No. 211436, on March 15, 2018, Corcept filed a Complaint against Teva alleging, *inter alia*, infringement of U.S. Patent No. 8,921,348 ("the '348 patent") and U.S. Patent No. 9,829,495 ("the '495 patent"). *See Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 18-3632 (RMB)(LDW) (D.N.J.), Dkt. No. 1. At about this time, the Patent and Exclusivity Information for NDA No. 202107, as provided by the

Orange Book, listed the '348 and '495 patents, and Teva's ANDA included a Paragraph IV certification as to each of the '348 and '495 patents.

18. As a direct and automatic result of its March 15, 2018 Complaint against Teva, Corcept triggered the statutorily mandated stay period, precluding the FDA from issuing a final approval of Teva's ANDA No. 211436 until the expiration of the stay period.

19. Corcept later amended its complaint to include in U.S. Patent No. 9,943,526 ("the '526 patent"). *See id.*, Dkt. No. 15.

20. The '348, '495, and '526 patents do not claim the drug mifepristone itself. Nor do they claim an FDA-approved method of using mifepristone. The only FDA-approved indication for Korlym is to treat hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery by administering a 300 mg tablet of mifepristone once daily with a meal.

21. Corcept knew that the '348, '495, and '526 patents claim methods of treating patients that are wholly disconnected from, and do not read on, the sole FDA-approved indication listed for Korlym and the proposed label for Teva's generic mifepristone product. Corcept knew that Teva would not directly infringe the patented methods by marketing its proposed product because Teva, a pharmaceutical company, does not treat patients. Corcept also knew that Teva would not indirectly infringe the patented methods by marketing its proposed product because, among other reasons, the *only* indication on Teva's label is for a use that does not infringe the '348, '495, or '526 patents.

22. As a result, that first lawsuit against Teva was so objectively baseless that no reasonable litigant could realistically have expected success on the merits. Rather, Corcept's true

purpose in initiating that lawsuit was to interfere directly with the business relationships of Teva under the pretext of its baseless claims, which were asserted to impermissibly broaden the scope of the '348, '495, and '526 patents, rather than as part of a legitimate effort to obtain judicial review. In fact, after Corcept filed subsequent cases involving additional patents and succeeded in consolidating those cases with this first-filed case—*see infra* Parts C and D—Corcept dropped its infringement claims as to the '348, '495, and '526 patents.

23. Corcept initiated and continued to prosecute the first infringement action solely to delay and prevent Teva from introducing its generic mifepristone product as a competitor to Korlym.

24. On or about October 12, 2018, the FDA tentatively approved Teva's ANDA No. 211436, concluding that Teva's proposed ANDA product is bioequivalent and therapeutically equivalent to Korlym. Tentative approval meant that the ANDA satisfied all the substantive requirements of 505(j)(2)(A) of the FFDCA but could not receive final approval because there was a period of Orphan Drug Act exclusivity for the listed drug and because of the 30-month stay based on Corcept's lawsuit.

25. The Orphan Drug Act exclusivity period for NDA No. 202107 expired on February 17, 2019. Accordingly, the only barrier to final FDA approval of Teva's product at that time was the 30-month stay, which was based on the pendency of Corcept's first lawsuit and would stay in effect until August 1, 2020.

C. Corcept Files Second Complaint Against Teva

26. Corcept, in an effort to further extend the life of its meritless lawsuit and thus preserve its monopoly on Korlym, then obtained and listed new patents in the Orange Book entry for Korlym—U.S. Patent No. 10,166,242 ("the '242 patent"), U.S. Patent No. 10,166,243 ("the '243 patent"), and U.S. Patent No. 10,195,214 ("the '214 patent"). Corcept's plan—which

succeeded—was to consolidate the second case with the first one and thereby delay the progress of the first case.

27. On February 8, 2019, Corcept filed a Complaint against Teva alleging, *inter alia*, infringement of the '242, '243, and '214 patents. *See* Civil Action No. 19-5066, Dkt. No. 1.

28. The '242, '243, and '214 patents do not claim the drug mifepristone itself. Nor do they claim an FDA-approved method of using mifepristone. The only FDA-approved indication listed for Korlym is to treat hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery by administering a 300 mg tablet of mifepristone once daily with a meal.

29. Corcept knew that the '242, '243, and '214 patents claim methods of treating patients that are wholly disconnected from, and do not read on, the sole FDA-approved indication listed for Korlym and the proposed label for Teva's generic mifepristone product. Corcept knew that Teva would not directly infringe the patented methods by marketing its proposed product because Teva, a pharmaceutical company, does not treat patients. Corcept also knew that Teva would not indirectly infringe the patented methods by marketing its proposed product because, among other reasons, the *only* indication on Teva's label is for a use that does not infringe the '242, '243, and '214 patents. Corcept has since dropped its infringement allegations regarding the '242 and '243 patents.

30. Corcept initiated the second infringement action solely to delay and prevent Teva from introducing its generic mifepristone product as a competitor to Korlym.

31. Corcept dropped the '526, '242, and '243 patents without even serving infringement contentions.

D. Corcept Files Third Complaint Against Teva

32. Corcept, continuing its efforts to further extend the life of its meritless lawsuit and thus preserve its monopoly on Korlym, obtained and listed a new patent in the Orange Book entry for Korlym—U.S. Patent No. 10,500,216 ("the '216 patent"). Corcept's goal in instituting this third civil action mirrored its goal in instituting the second case—*see supra* Part C—consolidate the third case with the first two cases and thereby delay the progress of the first case.

33. On December 13, 2019, Corcept filed a Complaint against Teva alleging, *inter alia*, infringement of the '216 patent. *See* Civil Action No. 19-21384, Dkt. No. 1.

34. At about this time, Teva's ANDA No. 211436 included a Paragraph IV certification as to each of the '348, '495, '526, '242, '243, and '214 patents, in addition to U.S. Patent Nos. 10,006,924, 10,151,763, 10,231,983, and 10,314,850.

35. The '216 patent does not claim the drug mifepristone itself. Nor does it claim an FDA-approved method of using mifepristone. The only FDA approved indication listed for Korlym is to treat hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery by administering a 300 mg tablet of mifepristone once daily with a meal.

36. Corcept knows that the '216 patent claims a method of treating patients that is wholly disconnected from, and does not read on, the sole FDA-approved indication listed for Korlym and the proposed label for Teva's generic mifepristone product. Corcept knows that Teva will not directly infringe the patented method by marketing its proposed product because Teva, a pharmaceutical company, does not treat patients. Corcept also knows that Teva will not indirectly infringe the patented method by marketing its proposed product because, among other reasons, the *only* indication on Teva's label is for a use that does not infringe the '216 patent.

37. Corcept initiated the third infringement action solely to delay and prevent Teva from introducing its generic mifepristone product as a competitor to Korlym.

38. Corcept dropped the '348 and '495 patents prior to serving expert reports on validity.

E. Corcept Files Fourth Complaint Against Teva

39. Corcept's latest effort to extend the life of its meritless lawsuit and thus preserve its monopoly on Korlym is this fourth civil action regarding the '800 and '801 patents. Corcept's goal in instituting this fourth civil action mirrors its goal in instituting the second and third cases—*see supra* Parts C and D—consolidate the fourth case with the previously filed cases and thereby delay trial in the consolidated case.

40. The '800 patent is titled "Concomitant administration of glucocorticoid receptor modulators and CYP3A inhibitors" and issued on November 24, 2020. The '801 patent is titled "Optimizing Mifepristone Absorption" and issued on November 24, 2020. Both patents were submitted to the Orange Book on or about November 24, 2020.

41. Upon information and belief, Corcept owns rights, title, and interests in and to the '800 and '801 patents.

42. On March 9, 2023, the Court held a status conference in the previously filed cases, which have been consolidated, and directed the parties to submit a proposed date for submission of the pretrial order and trial date for the consolidated case by March 17, 2023.

43. On March 17, 2023, Corcept filed a Complaint against Teva alleging, *inter alia*, infringement of the '800 and '801 patents. *See* Civil Action No. 23-1505, Dkt. No. 1. That same day, the parties submitted a letter to the Court proposing a September 2023 trial date. In the same letter, Corcept suggested that, in the event that this most recently filed case is consolidated with the earlier cases, trial should be delayed until December 2023.

44. The ’800 and ’801 patents do not claim the drug mifepristone itself. Nor do they claim an FDA-approved method of using mifepristone. The only FDA approved indication listed for Korlym is to treat hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing’s syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery by administering a 300 mg tablet of mifepristone once daily with a meal.

45. Corcept knows that the ’800 and ’801 patents claim methods of treating patients that are wholly disconnected from, and do not read on, the sole FDA-approved indication listed for Korlym and the label for Teva’s generic mifepristone product. Corcept knows that Teva will not directly infringe the patented methods by marketing its ANDA product because Teva, a pharmaceutical company, does not treat patients. Corcept also knows that Teva will not indirectly infringe the patented methods by marketing its ANDA product because, among other reasons, the *only* indication on Teva’s label is for a use that does not infringe the ’800 and ’801 patents.

46. Corcept initiated the instant infringement action solely to delay resolution of the overall dispute and prevent Teva from introducing its generic mifepristone product as a competitor to Korlym.

COUNT I: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’800 PATENT

47. Teva incorporates by reference, as though fully set forth herein, paragraphs 1 through 46 of the counterclaims.

48. There is an actual, substantial, continuing, and justiciable controversy between Teva and Corcept regarding whether Teva’s submission of ANDA No. 211436 and/or Teva’s manufacture, use, offer to sell, or sale of the Teva ANDA Product has infringed or will infringe

any valid or enforceable claim of the ’800 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

49. Teva has not infringed any valid and enforceable claim of the ’800 patent either literally or under the doctrine of equivalents.

50. Teva is entitled to a declaration by the Court that it does not infringe any valid and enforceable claim of the ’800 patent.

51. Teva is entitled to further necessary or proper relief based on the Court’s declaratory judgment or decree.

COUNT II: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’801 PATENT

52. Teva incorporates by reference, as though fully set forth herein, paragraphs 1 through 51 of the counterclaims.

53. There is an actual, substantial, continuing, and justiciable controversy between Teva and Corcept regarding whether Teva’s submission of ANDA No. 211436 and/or Teva’s manufacture, use, offer to sell, or sale of the Teva ANDA Product has infringed or will infringe any valid or enforceable claim of the ’801 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

54. Teva has not infringed any valid and enforceable claim of the ’801 patent either literally or under the doctrine of equivalents.

55. Teva is entitled to a declaration by the Court that it does not infringe any valid and enforceable claim of the ’801 patent.

56. Teva is entitled to further necessary or proper relief based on the Court’s declaratory judgment or decree.

COUNT III: DECLARATORY JUDGMENT OF INVALIDITY OF THE '800 PATENT

57. Teva incorporates by reference, as though fully set forth herein, paragraphs 1 through 56 of the counterclaims.

58. Corcept has alleged in this action that Teva infringed the '800 patent by filing ANDA No. 211436 and that Teva's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Teva's ANDA Product would infringe the '800 patent.

59. The '800 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created basis for invalidation.

60. Accordingly, a present, genuine, and justiciable controversy exists between Teva and Corcept regarding the validity of the claims of the '800 patent.

61. Teva is entitled to a declaration by the Court that one or more of the claims of the '800 patent are invalid.

62. Teva is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

COUNT IV: DECLARATORY JUDGMENT OF INVALIDITY OF THE '801 PATENT

63. Teva incorporates by reference, as though fully set forth herein, paragraphs 1 through 62 of the counterclaims.

64. Corcept has alleged in this action that Teva infringed the '801 patent by filing ANDA No. 211436 and that Teva's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Teva's ANDA Product would infringe the '801 patent.

65. The '801 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, 112, and/or any other judicially created basis for invalidation.

66. Accordingly, a present, genuine, and justiciable controversy exists between Teva and Corcept regarding the validity of the claims of the ’801 patent.

67. Teva is entitled to a declaration by the Court that one or more of the claims of the ’801 patent are invalid.

68. Teva is entitled to further necessary or proper relief based on the Court’s declaratory judgment or decree.

PRAYER FOR RELIEF

WHEREFORE, Teva prays that the Court enter judgment ordering as follows:

(a) adjudicating and declaring that the ’800 and ’801 patents are invalid;

(b) adjudicating and declaring that the filing of ANDA No. 211436 was not an act of infringement of the ’800 and ’801 patents under 35 U.S.C. § 271(e);

(c) adjudicating and declaring the manufacture, use, sale, or offer for sale, within the United States, or importation into the United States of the drug product described in ANDA No. 211436 will not infringe, directly or indirectly, the ’800 and ’801 patents under 35 U.S.C. § 271(a)–(c);

(d) awarding Teva its reasonable attorney’s fees and costs reasonably incurred in prosecuting this action pursuant to 35 U.S.C. § 285; and

(e) granting Teva such other and further relief as the Court deems just and appropriate.

Dated: May 2, 2023

Of Counsel:

J.C. Rozendaal (*pro hac vice* to be submitted)
Michael E. Joffre (*pro hac vice* to be submitted)
Uma N. Everett (*pro hac vice* to be submitted)
William H. Milliken (*pro hac vice* to be submitted)
Brady P. Gleason (*pro hac vice* to be submitted)
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue NW, Suite 600
Washington, DC 20005
(202) 371-2600

By: /s/ *Liza M. Walsh*
Liza M. Walsh
Christine I. Gannon
Jessica K. Formichella
Lauren R. Malakoff
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100
(973) 757-1090

Attorneys for Defendant
Teva Pharmaceuticals USA, Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2 and 40.1

Defendant Teva Pharmaceuticals USA, Inc., by its undersigned counsel, hereby certifies that the matter in controversy is the subject of the following pending action: *Corcept Therapeutics v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 18-3632 (RMB)(LDW) (D.N.J.).

The matter in controversy is not subject to any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: May 2, 2023

By: /s/ *Liza M. Walsh*

Liza M. Walsh
Christine I. Gannon
Jessica K. Formichella
Lauren R. Malakoff
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100
(973) 757-1090

Attorneys for Defendant
Teva Pharmaceuticals USA, Inc.

Of Counsel:

J.C. Rozendaal (*pro hac vice* to be submitted)
Michael E. Joffre (*pro hac vice* to be submitted)
Uma N. Everett (*pro hac vice* to be submitted)
William H. Milliken (*pro hac vice* to be submitted)
Brady P. Gleason (*pro hac vice* to be submitted)
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue NW, Suite 600
Washington, DC 20005
(202) 371-2600

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendant Teva Pharmaceuticals USA, Inc., by its undersigned counsel, hereby certifies that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: May 2, 2023

By: /s/ *Liza M. Walsh*

Liza M. Walsh
Christine I. Gannon
Jessica K. Formichella
Lauren R. Malakoff
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100
(973) 757-1090

Attorneys for Defendant
Teva Pharmaceuticals USA, Inc.

Of Counsel:

J.C. Rozendaal (*pro hac vice* to be submitted)
Michael E. Joffre (*pro hac vice* to be submitted)
Uma N. Everett (*pro hac vice* to be submitted)
William H. Milliken (*pro hac vice* to be submitted)
Brady P. Gleason (*pro hac vice* to be submitted)
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue NW, Suite 600
Washington, DC 20005
(202) 371-2600